

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 EA-10 NEA-09 ISO-00 OES-05

RSC-01 /060 R

66616

DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

NEA/IAI:EWBIZIC (INFO)

ARA/NSC-IG:RJBLOOMFIELD(INFO)

EA/RA:CCHAPMAN(INFO)

AF/RA:JAANDEREGG (INFO)

EUR/NSC-IG:JROUSE (INFO)

----- 098339

R 082122Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY BANJUL

AMEMBASSY NAIROBI

AMEMBASSY PRETORIA

AMEMBASSY CANBERRA

AMEMBASSY SINGAPORE

AMEMBASSY SEOUL

AMEMBASSY TAIPEI

AMEMBASSY TOKYO

AMEMBASSY PARIS

AMEMBASSY MADRID

AMEMBASSY TEL AVIV

AMEMBASSY ROME

AMEMBASSY VIENNA

AMEMBASSY BONN

AMEMBASSY COPENHAGEN

AMEMBASSY LONDON

AMEMBASSY BRASILIA

AMEMBASSY BUENOS AIRES

AMEMBASSY BOGOTA

AMEMBASSY CARACAS

AMEMBASSY LIMA

AMEMBASSY MEXICO

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AMEMBASSY SAN JOSE

AMCONSUL HONG KONG

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E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, XX

SUBJECT: RECALL OF INCORRECTLY MANUFACTURED AND INCORRECTLY
LABELED MEDICAL DEVICE.

1. FDA ADVISES THAT THE AMES COMPANY, DIVISION OF MILES LABORATORIES,

INC., ELKHART, INDIANA 46514 IS RECALLING ALL DIAL FACES FOR THE
AMES BLOOD ANALYZER, MODELS 6200 AND YEPPM THERE ARE FOURTEEN
DIFFERENT DIAL FACES, ONE FOR EACH OF FOURTEEN TESTS USED TO MEASURE
THE CHEMICAL CONSTITUENTS OF HUMAN BLOOD SERUM OR PLASMA AND OTHER
BODY FLUIDS. EACH DIAL FACE HAS THE NAME OF THE TEST AND A
CALIBRATED SCALE PRINTED ON IT. EACH DIAL FACE IS ALSO NOTCHED
IN A SPECIFIC WAY TO MECHANICALLY ACTIVATE THE INSTRUMENT
TO GIVE A READING ON THE CALIBRATED SCALE. THE DIAL FACES ARE
BEING RECALLED BECAUSE OF TWO PROBLEMS. SOME OF THE DIAL FACES
HAVE THE NAME OF ONE TEST AND THE CALIBRATED SCALE OF A DIFFERENT
TEST PRINTED ON IT. ALSO, SOME OF THE DIAL FACES HAVE NO
NOTCHES. THIS "REVERSE" NOTCHING WILL RESULT IN INCORRECT
READINGS OF THE CALIBRATED SCALE.

2. INASMUCH AS DISTRIBUTION IS WORLDWIDE, POSTS ARE REQUESTED
TO CHECK WITH MARKET MANAGERS AS DETAILED BELOW (THESE MARKET
MANAGERS ARE RESPONSIBLE FOR SPECIFIC AREAS OF DISTRIBUTION
THROUGHOUT THE WORLD) TO DETERMINE IF THE ULTIMATE RECIPIENTS
OF THE MEDICAL DEVICE HAVE BEEN INFORMED OF THE DETAILS OF
THE RECALL.

3. AFRICA:

MARKET MANAGER:

R. ELLIS

MARKET AREA:

ANGOLA, MALAWI, MOZAMBIQUE,
RHODESIA, SOUTH AFRICA,
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LESOTHO (BASUTOLAND),
BOTSWANA (BECHUANALAND)
ST. HELENA ISLANDS, SOUTH-
WEST AFRICA, SWAZILAND

ADDRESS:

P. O. BOX 17479
HILLBROW

TRANVAAL
SOUTH AFRICA

MARKET MANAGER:
K. WILSON

MARKET AREA:
ETHIOPIA, KENYA, MALIGASY
REPUBLIC, MAURITIUS, SUDAN, TANZANIA, UGANDA, UNITED
ARAB REPUBLIC, ZAMBIA, BURUNDI, FRENCH SOMALILAND,
RWANDA, SEYCHELLES ISLAND,
SOMALI REPUBLIC

ADDRESS:
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O.O. BOX 30467
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CENTRAL AFRICAN REPUBLIC, CHAD, CONGO (BRAZZAVILLE), DAHOMEY,
EQUATORIAL GUINEA, GAMBIA, GUINEA, MALI, NIGER, PORTUGUESE
GUINEA, SAO TOME AND PRINCIPE, SENEGAL, TOGO, UPPER VOLTA

ADDRESS:
P. O. BOX 585
BANJUL, THE GAMBIA
WEST AFRICA

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4. ASIA:

MARKET MANAGER:
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MARKET AREA:
ADEN, AFGHANISTAN, BANGLADESH, CANTON, ENDERBURY ISLANDS,
COCOS (KREELING ISLANDS), INDIA, INDONESIA, IRAQ, MALAYSIA,
MALDIVE ISLANDS, MUSCAT AND OMAN, NEPAL, PORTUGUESE TIMOR,
SIKHIM, SINGAPORE, SRI LANKA, SOUTH ARABIA, SYRIA, TRUCIAL STATES,
WEST IRIAN, THAILAND, YEMEN

ADDRESS:
AMES COMPANY
ROOM 523 TANGLIN

SHOPPING CENTER
TANGLIN ROAD, SINGAPORE

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FIJI ISLANDS, FRENCH POLYNESIA, HONG KONG, JOHNSTON ISLAND,
LAOS, MACAO, MARIANAS ISLANDS, MARSHALL ISLANDS, MIDWAY ISLANDS,
MONGOLIA, NAURU, NEW CALEDONIA, NEW HEBRIDES, PITCAIRN ISLAND,
TONGA, VIETNAM, WAKE ISLAND, WESTERN SAMOA, PAKISTAN, PHILIPPINES

ADDRESS:
AMES CO, C/O MULLER AND PHIPPS (CHINA)
LTD., P. O. BOX 25
CHATER ROAD, HONG KONG

MARKET MANAGER:
N. J. HOBSON

MARKET AREA:
AUSTRALIA, NEW ZEALAND, NEW GUINA, NORFOLK ISLAND, PAPUA

ADDRESS:
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MILES LABORATORIES
AUSTRALIA PTY., LTD.
WELLINGTON ROAD,
MULGRAVE, VICTORIA AUSTRALIA 3170

MARKET MANAGER:
M. TANEMURA

MARKET AREA:
JAPAN

ADDRESS:
MILES - SANKYO CO., LTD., CHUO, DAIWA BLDG.
13-13, GINZA
1-CHOME, CHUO-KU,
TOKYO 104, JAPAN

MARKET MANAGER:
T. HJM KIM

MARKET AREA:
KOREA

ADDRESS:

C/O HAN-IL PHARMA EUTICAL INDUSTRIES CO., LTD.
P. O. BOX CENTRAL 18,
SEOUL, KOREA

MARKET MANAGER:

H. H. LEE

MARKET AREA:

TAIWAN

ADDRESS:

AMES DIVISION MILES SANKYO CO., LTD.,
C/O CHINA CHEMICAL AND PHARMACEUTICAL CO., LTD.
9TH FLOOR, #7, SECTION 1, ROOSEVELT ROAD,
TAIPEI, TWIWAN

5. EUROPE:

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MARKET MANAGER:

S. D. MARTIN

MARKET AREA:

BELGIUM, FRANCE, LUXEMBURG, MONACO, MOROCCO, NETHERLANDS,
TUNISIA

ADDRESS:

LABORATOIRES MILES S.A., TOUR, MAINE,
MONTPARNASSE 75755
PARIS, CEDEX 15, FRANCE

MARKET MANAGER:

C. PEREZ

MARKET AREA:

AZORES, PORTUGAL, SPAIN

ADDRESS:

MILES-MARTIN LABS DEPARTAMENTO AMES,
CALLE GRANADA #38,
MADRID 7, SPAIN

MARKET MANAGER:

A. EILAT

MARKET AREA:

IRAN, ISRAEL, TURKEY

ADDRESS:

AMES CO., DIVISION MILES LABS ISRAEL LTD.
64 LEVY ESHKOL STREET
P.O. BOX 17160
TEL AVIV 69371, ISRAEL

MARKET MANAGER:

A. SABATO

MARKET AREA:

CYPRUS, GIBRALTAR, GREECE, ITALY, LICHTENSTEIN, MALTA,
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SAN MARINO, SWITZERLAND

ADDRESS:

MILES ITALIANA DIVISIONE AMES,
CORSO VENEZIA, 14,
MILAN, ITALY

MARKET MANAGER:

K. IFKOVITS

MARKET AREA:

ALBANIA, BULGARIA, CZECHOSLOVAKIA, EAST GERMANY, HUNGARY,
POLAND, RUMANIA, RUSSIA, YUGOSLAVIA

ADDRESS:

MILES - AMES INFORMATIONSBURO 19,
GUNOLDSTRASSE 14, A-1199
WIEN, AUSTRIA

MARKET MANAGER

R. G. SENGHASS

MARKET AREA:

AUSTRIA, WEST GERMANY

ADDRESS:

MILES GMBH, SPARTE AMES,
6000 FRANKFURT-AM-MAIN,
LYONERSTRASSE 36, WEST GERMANY

MARKET MANAGER:

J. MADSEN

MARKET AREA:

DENMARK, FINLAND, ICELAND, NORWAY, SWEDEN

ADDRESS:

MILES SCANDENAVIA
HOVEDGADEN 49
BIRKERROD, DENMARK

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MARKET MANAGER:

R. SPEIGHT

MARKET AREA:

EIRE, UNITED KINGDOM, CHANNEL ISLANDS

ADDRESS:

MILES LABORATORIES, LTD.,
STOKE COURT,
STOKE POGES, SLOUGH,
BUCKINGHAMSHIRE, ENGLAND

6. LATIN AMERICA:

MARKET MANAGER:

R. E. HERMIDA

MARKET AREA:

ARGENTINA, PARAGUAY, URAGUAY

ADDRESS:

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S.R.L.J.M. CAMPOS Y PASAJE MAESTRO ALFREDO SCHIUMA,
CASILLA DE CORREOS 1497,
SAN ANDRES F.C.G.B.M.
BUENOS AIRES, ARGENTINA

MARKET MANAGER:

R. D. PANTIN

MARKET AREA:

BRAZIL

ADDRESS:

LABORATORIOS MILES DO BRAZIL, LTDA.
RUA ALM. PEREIRA GUIMARES 313,
CAIXA POSTAL 5999,
SAO PAULO, S.P. BRAZIL

MARKET MANAGER:

F. MONTOYA
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MARKET AREA:
COLOMBIA

ADDRESS:
MILES LABORATORIES PAN AMERICAN, INC.
SUCURSAL DE COLOMBIA AVENIDA 6, #29, N-95
APARTADO AEREO 1955
CALI (VALLE). COLOMBIA

MARKET MANAGER:
R. LOPEZ

MARKET MARKET AREA:
VENEZUELA

ADDRESS:
PRODUCTOS MILES C.A.
APARTADO #80025
CARACAS, VENEZUELA

MARKET MANAGER:
J.E. ASCOLI

MARKET AREA:
BRITISH HONDURAS, CUBA, COSTA RICA, EL SALVADOR, GUATEMALA,
HONDURAS, NICARAGUA, PANAMA CANAL ZONE, PANAMA REPUBLIC

ADDRESS:
APARTADO # 7-2800
SAN JOSE, COSTA RICA

MARKET MANAGER:
A. BOY

MARKET AREA:
MEXICO

ADDRESS:
INSTITUTO MILES DE TERAPEUTICA EXPERIMENTAL DIVISION DE
LABORATORIOS MILES DE MEXICO S. A.,
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DE CMD. CALZADA, XOCHIMILCO 77
APARTADO #22026 MEXICO
22 D.F., MEXICO

MARKET MANAGER:

J. E. BRAUN

MARGET AREA:

BOLIVIA, CHILE, ECUADOR, PERU

ADDRESS:

RICHARD O. CUSTER,

S.A., CASILLA 681

LIMA, PERU

KISSINGER

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Message Attributes

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Margaret P. Grafeld
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US Department of State
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05 JUL 2006

Review Media Identifier:
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Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: RECALL OF INCORRECTLY MANUFACTURED AND INCORRECTLY LABELED MEDICAL DEVICE.
TAGS: ETRD, EIND, TBIO, XX, AMES CO
To: BANJUL MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006